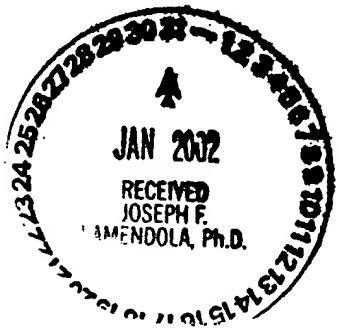
EXHIBIT VII

FDA LETTER ACKNOWLEDGING RECEIPT OF
NDA # 21-445

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857



NDA 21-445

Schering Corporation, agent for
MSP Singapore Co. LLC
Attention: Joseph F. Lamendola, Ph.D.
Vice President
U.S. Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

Dear Dr. Lamendola:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Zetia (ezetimibe) Tablets, 10 mg

Date of Application: December 27, 2001

Date of Receipt: December 27, 2001

Our Reference Number: NDA 21-445

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on February 25, 2002, in accordance with 21 CFR 314.101(a). If the application is filed as a standard review, the user fee goal date will be October 27, 2002.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). As discussed at the meeting of April 25, 2001, we are hereby granting a deferral of pediatric studies for patients ≥ 10 years of age and a waiver of pediatric studies on patients < 10 years of age.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" (PPSR) FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. Please note

that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

We acknowledge your Proposed Pediatric Study Requests, submitted to IND 52,791, dated April 24, 2000, and September 26, 2001, and refer you to our letter dated November 1, 2001, which stated that before a written request could be issued, we would need to complete the review of the final study reports from Phase 3 studies of this drug submitted in a New Drug Application.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room, Room 14B-19
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-6412.

Sincerely, /s/

{See append

William Koch
1/25/02 02:41:27 PM

William C. Koch, R.Ph.
Regulatory Project Manager
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

21-445

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/s/

William Koch
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